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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,795	03/10/2004	Carlos R. Plata-Salaman	ORT-1575CON	4508

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,795	PLATA-SALAMAN ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants Amendment filed October 13, 2005 is acknowledged. Claims 1-32 remain under consideration.

In the last Office Action claims 1-32 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent 6,589,985.

Applicants argue while a movement disorder might result from damage to the nervous system leading to cell death, this is not a necessary part of a movement disorder. Applicants urge neurodegenerative disorders by definition involve the death or damage to the cells of the nervous system.

Applicants' arguments are not persuasive and the rejection of record under the judicially created doctrine of obviousness-type double patenting is maintained. By Applicants' own admission, i.e., "neurodegenerative disorders by definition involve the death or damage to the cells of the nervous system", those disorders recited in claims 20-22 of the patent involve death or damage to cells of the nervous system.

The rejection of record under 35 U.S.C. 112, second paragraph, as set forth in the last Office Action, is withdrawn following the deletion of parenthetical subject matter.

In the last Office Action claims 1-32 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims are directed to the prevention and treatment of any neurodegenerative disorder and numerous pathologies as recited in claims 20-31. The specification provides support for cell survival rates following the administration of an enantiomer of instant Formula Ib

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and IIb and transient cerebral ischemia in a rat model following administration of a compound of Formula Ib. It was asserted the instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation.

Applicants argue the specification states acute and chronic neurodegenerative disorders are associated with neuronal cell death or compromise all of which result in the death or the serious compromise of the function of nerve cells. Further, Applicants urge the disclosed apoptotic mechanisms are characteristic of the causes of neuronal loss in many diverse neurodegenerative disorders. Applicants cite Example 2 as teaching a reduction in the volumes of neuronal injury or infarction after transient cerebral ischemia due to middle cerebral artery occlusion and state this model *would imply* efficacy in stroke and many other related pathological states.

Applicants' arguments have been given careful consideration but are not found persuasive. Applicants' position is prophetic and the rejection of record under 35 U.S.C. 112, first paragraph, is repeated for the reasons of record.

The Examiner is in agreement with Applicants' statements concerning acute and chronic neurodegenerative disorders being associated with neuronal cell death or compromise which result in the death or the serious compromise of the function of nerve cells, as well as apoptotic mechanisms being characteristic of the causes of neuronal loss in many diverse neurodegenerative disorders. Apoptotic mechanisms also extend to the function of other unrelated organ systems. However, Applicants' quantum leap to a prevention of any neurodegenerative disorder is unsupported by their

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disclosure. While deletion of the term "prevention" will not obviate the rejection of record, a claim directed to the treatment of cerebral ischemia would be given favorable consideration. Reasonable expectations of success are absent with respect to treatment modalities for the claimed non-ischemic diseases.

Claims 1-20 and 27 were rejected under 35 102(b) in the last Office Action as being anticipated by Choi et al., U.S. Patent 5,854,283. It was asserted Choi teaches the administration of compounds of instant Formula I and II to treat disorders of the central nervous system that characterize neurodegenerative disorders.

Applicants argue convulsions, epilepsy, stroke and muscle spasm are symptoms of some neurodegenerative disorders.

The rejection of record under 35 U.S.C. 102(b) is withdrawn because a clear teaching of treatment of neurodegenerative disorders is absent.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire **THREE MONTHS** from the mailing date of this Action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585.

The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 8, 2006



Phyllis G. Spivack

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**PHYLLIS SPIVACK
PRIMARY EXAMINER**